REMARKS

Finally rejected claims 65-91 have been replaced with new claims 92-141. It is to be noted that all of the new claims are method claims. In particular, Independent claims 92 and 93 relate to a method for enhancing an immune response to an antigen administered to a human or animal.

Before discussing the issues raised by the examiner in the final office action, applicant first wishes to thank the examiner for the courtesy extended to the below signed attorney during the interview on October 1, 2003. The following remarks constitute a separate record of the substance of the interview as well as additional comments in support of the patentability of the claimed invention.

The examiner has rejected claims 65-72 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In rejecting the claims the examiner notes that the adjuvant composition of claim 65 recites that the composition elicits an immune response when administered to an animal without reciting the presence of an antigen in the claimed composition. The examiner urges that it is unclear as to how the claimed combination of monoglyceride and fatty acid would elicit an immune response without the presence of an antigen.

In response to this rejection applicant has replaced the rejected composition claims with a set of method claims. It is to be noted that each of the method claims relate to a method of enhancing an immune response in a human or animal **"to an antigen administered to said human or animal"**. It is therefore self-evident that the examiner's concern regarding the enhanced

immune response without the presence of an antigen is not applicable to these new claims. Accordingly, applicant submits that the present claims are now in full compliance with 35 U.S.C. § 112.

The examiner has rejected claims 65-76, 78-82 and 84-89 under 35 U.S.C. § 102(b) as being anticipated by Isaacs. In rejecting the claims the examiner urges that the antiviral composition of Isaacs anticipates the composition of the rejected claims.

In response to this rejection all of the composition claims have been replaced by appropriate method claims which are directed toward a method for enhancing an immune response in a human or animal. It was agreed during the interview that although the examiner believes that Isaacs' composition anticipates the composition used in applicant's invention, Isaacs does not disclose or suggest the use of the composition for enhancing an immune response in a human or animal. Thus it is clear that the anticipation rejection based on Isaacs is not appropriate for a presently claimed method.

The examiner has rejected claims 65-91 under 35 U.S.C. § 103(a) as being unpatentable over WO 93/06921 by itself in combination with Amselem, Wright, Koga, Carrano individually or in combination.

In response to this rejection applicant has replaced all of the composition claims with method claims. In addition, it is to be noted that the adjuvant recited in each of the method claims is in the form of an emulsion. Support for the emulsion form of the invention is found on page 6, lines 31-32 wherein it states that oil droplets of about 1 micron in size form emulsions, and the examples on

page 3 which establish that the droplets in the suspensions of the present invention are within the size range of particles which form emulsions.

The below signed attorney emphasized during the interview that the emulsions used in the present invention are sharply distinguished over the non-emulsions utilized by the primary reference. In this regard it is to be noted that the primary reference (WO 93/06921) clearly states on page 4 that "The current invention is thus easily and **sharply distinguished from** both liposomes, **emulsions**, microemulsions, as well as various microencapsulated emulsions, hydrogels and reversed micelles".

In view of the emulsions used in the presently claimed method and further in view of the fact that the primary reference specifically teaches against the use of emulsions, it is self-evident that the presently claimed invention is not disclosed or suggested by WO 93/06921 by itself or in combination with the secondary references.

The only remaining rejection is the rejection of claims 65-91 under 35 U.S.C. § 103(a) as being unpatentable over the same primary and secondary references relied upon by the examiner in the above-discussed obviousness rejection and further in view of Isaacs relied upon in the above-discussed anticipation rejection. Applicant submits that this rejection is no longer appropriate in view of the non-emulsion formulation required by the primary reference as discussed above and further in view of the fact that Isaacs does not disclose or suggest the presently claimed method of enhancing an immune response in a human or animal.

In addition to the above-discussed distinguishing features of the invention over the prior art, it is also to be noted that claims 93 and all of the claims which depend therefrom (i.e., claims 118 through 141 more particularly require that the concentration of fatty acid in the adjuvant is 10% or more. In this regard it will be recalled that the primary reference, at best contains an inherent amount of only 1% free fatty acid. None of the references, either alone or in combination with each other disclose or suggest that the amount of fatty acids should be at least 10% as recited in the aforementioned claims.

In view of the above arguments and further amendments to the claims, applicant respectfully requests reconsideration and allowance of all of the claims which are currently pending in the application.

Respectfully submitted,

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